STATEMENT OF CONGRESSMAN HENRY A. WAXMAN

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (NAPM)
Tuesday, June 23, 1998 ~ Four Seasons Hotel, Washington DC

Thank you. It is really a pleasure to join you this afternoon.

I wanted to talk to you about issues of mutual concern that are on the horizon, including the future of the 1984 Waxman/Hatch Act.

Looking back to 1984, the success of the Act has truly exceeded my expectations. Generic drugs save billions of dollars in health care expenditures for consumers, HMOs and insurers, pharmacy benefit managers and, of course, the Federal government. Today, America is unique in having a thriving and competitive generic drug industry.

At the same time, the brandname industry has prospered like never before. The pharmaceutical industry remains the most profitable industry in the world. In fact, PhRMA *[pronounced "FAR-Ma"]* boasted recently that its research spending has tripled in the past ten years.

As you know, the reason the Act has succeeded in helping consumers is because it strikes a careful balance between promoting innovation and ensuring that consumers have timely access to affordable medicines. This balance rests on the Act's clear and fair standards for the approval of generic drugs and for the granting of prescription drug patent term extensions.

CHANGES TO WAXMAN/HATCH

Of course, no law is perfect. I know there is interest in revisiting the Act. The trade press reported recently that PhRMA has been courting patient groups, trying to win them over to their view of what needs to be done to the Waxman/Hatch Act. PhRMA says it "intends over the next couple of years to have a fairly intense effort to modify the Act."

What PhRMA wants is just one side of the coin. On numerous occasions, I and my colleague Senator Hatch have publicly emphasized that any revisions to the 1984 Act must be made in the same spirit and to the same effect as the original statute. I would strongly oppose any proposals which would upset the existing balance of commercial and public interests sustained by the Waxman/Hatch Act. Before anything, all of the interested parties should recall the Hippocratic admonition, "First, do no harm."

But that has not stopped others from trying to tip that balance in their own favor. In the past few years, there have been numerous efforts to obtain special patent extensions and special extensions of market exclusivity in direct contravention of the Waxman/Hatch Act and its underlying purpose. Some of these efforts have literally taken place in the dead of night.

For example, one patent extension was smuggled into the conference report of the 1997 Kennedy- Kassebaum Health Care Reform Act. Only strenuous, last minute efforts by Senators Kennedy, Wellstone and Pryor, prevented it from becoming law.

Last year, there was a very creative proposal to grant patent extensions in exchange for a 3 percent "kickback" to the NIH to fund research. This was a shameless effort by a few prescription drug companies to piggyback their own financial interests on the important cause of biomedical research. Thankfully, this attempt to clothe naked self-interest in the appearance of respectability didn't fool the press or the Congress. The cold reality was that it would have been consumers who pay out of pocket for their drugs, especially older Americans, who would have borne the brunt of this $750 million windfall.

The latest effort to change the Waxman/Hatch Act took place last month. The House Judiciary Subcommittee on Courts and Intellectual Property held a hearing which addressed many issues -- including a proposal to undercut the Waxman/Hatch Act. Congressman Pete Stark and I reviewed this proposal and submitted a statement in opposition to the hearing record.

The proposal in question has been championed by Schering Plough. For several years, Schering has been lobbying aggressively for patent extensions for its anti-histamine, Claritin. Last year, Claritin had over $900 million in domestic sales.

The Schering proposal would have established an administrative process at the Patent Office for the resolution of prescription drug patent extension claims. But such a process would serve as an invitation to undercut the scientific judgments made by the FDA and its advisory committees. Any company could come to the Patent Office and claim that FDA was wrong on the science, and therefore a patent extension was needed to compensate the company for lost patent time.

But what is "lost time"? How is the Patent Office supposed to second-guess the FDA and its scientific advisors over complicated questions like "How large should a clinical trial be?" And when are questions about toxicity or carcinogenicity legitimate or not? Today, none of this is up to the Patent Office to decide, and it never should be.

This long history of subversive lobbying by brandname companies makes me very cautious when they claim they want to help consumers in reopening the Waxman/Hatch Act.

Today, the combination of Waxman/Hatch patent extensions, Prescription Drug User Fee drug approval deadlines, and recent FDA reforms ensures that new drugs are approved quickly and enjoy full terms of patent protection and market exclusivity.

If PhRMA comes back to Congress looking for more, they must be prepared to work with you and with us on maintaining the balance of interests which has made the Waxman/Hatch Act such a success. This means you must be prepared to educate consumers, patients, and

Congress about the way the Act has allowed you to do business and help control healthcare costs. This also means you must think very carefully about what changes -- if any -- your industry is prepared to accept or advocate in the Act.

CONCLUSION

Let me conclude by saying this. We are in an election year. That means a lot of things, but it always means a short session for the Congress. So we don't have many days to act on an agenda that offers unusual opportunity for some very positive steps for the American people.

We can enact tobacco reform legislation. We can address quality and consumer health care rights responsibly. But in the absence of careful congressional deliberation this term, I don't believe there is adequate time to consider changes to the Waxman/Hatch Act.

I hope all of you will be extremely active in the coming year to educate the Congress and to ensure no harm is done to the Waxman/Hatch Act.

Thank you.

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